Amend claims 5-10, and 13, as follows:

5. (Twice amended) The article of manufacture of claim 1 or 2 wherein the PDE5 inhibitor further has



- (i) at least a 100 fold differential in IC_{50} values for the inhibition of PDE5 versus PDE6, and
- (ii) at least 1000 fold differential in IC_{50} values for the inhibition of PDE5 versus PDE1c.
- 6. (Twice amended) The article of claim 1 or 2 wherein the oral dosage form comprises about 1 mg, about 2 mg, about 5 mg, or about 10 mg, of the PDE5 inhibitor.
- 7. (Twice amended) The article of claim 1 or 2 wherein the chronic dosing regimen is a daily dosing regimen.
- 8. (Twice amended) The article of claim 1 or 2 wherein the chronic dosing regimen comprises administration of about 1 mg/day to about 10 mg/day of the PDE5 inhibitor.
- 9. Twice amended) The article of claim 1 or 2 wherein the package insert provides a maximum dosage of the PDE5 inhibitor of about 10 mg per day.
- 10. (Twice amended) The article of claim 1 or 2 wherein the PDE5 inhibitor is selected from the group consisting of

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(6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione; and

 $(3S, 6R, 12aR) \neq 2, 3, 6, 7, 12, 12a-hexahydro-2, 3-dimethyl-6-$

(3,4-methy/enedioxyphenyl)pyrazino[2',1':6,1]pyrido-

[3,4-b] in dole-1,4-dione.

13. (Twice amended) The article of claim 1 or 2 wherein the PDE5 inhibitor has the structure

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Add new claims 19 and 20:



- 19. An article of manufacture for human pharmaceutical use comprising:
- (a) an oral dosage form comprising a PDE5 inhibitor having an IC_{50} for the inhibition of PDE5 less than 10 nM, and sufficient bioavailability to be effective in about 1 to about 10 mg unit oral dosages;
- (b) a package insert providing that the PDE5 inhibitor is useful to treat sexual dysfunction in a patient in need thereof by utilizing a chronic dosing regimen; and
 - (c) a container.

20. An article of manufacture for human pharmaceutical use comprising:

(a) an oral dosage form comprising a PDE5 inhibitor having an IC₅₀ less than 10 nM, and a sufficient bioavailability to be effective in about 1 to about 10 mg unit oral dosages;

(b) a package insert providing that the PDE5 inhibitor is useful to treat sexual dysfunction in a patient in need thereof by utilizing a daily dosing regimen, and

(c) a container.